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TITLE: Randomized, Controlled Trial of CBT Training for PTSD Providers

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14. ABSTRACT

The purpose of this 4 year,randomized trial and comparative effectiveness study is to design, implement and evaluate a cost effective, web based self paced training program to provide skills-oriented continuing education for mental health professionals. The objective is to learn *whether novel, internet-based training methods, with or without web-centered supervision, may provide an effective means to train increasing numbers of mental health providers in relevant, evidence-based clinical skills*. The study will launch during the first quarter of the second year grant cycle. There are no research findings to date.

15. SUBJECT TERMS
There are no risks associated with participation.

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INTRODUCTION

Psychologically-based treatments and cognitive behavioral therapy (CBT) interventions have been shown to be effective in alleviating symptoms of Post-Traumatic Stress Disorder (PTSD) and related psychological health difficulties in Veterans and military personnel who suffer from these problems. To meet the increased service needs of Veterans with PTSD, new training methods need to be developed which are: 1) evidence-based, and *2)* effective in modifying and sustaining changes in provider behavior. Methods of training/implementation must also be scalable, and feasible for delivery to large numbers of providers in cost-effective ways. Internet-based training is a promising new approach for meeting this need, but has received little systematic evaluation to date. Noting the urgency and high priority of this issue, Fairburn and Cooper (2011) have advocated strongly for the development of novel, internet-based training methods and innovative research designs to test the effectiveness of these new training methods. Our current program of research is aimed to address these needs.

The broad objective of our research is to design, implement and evaluate scalable and cost-effective new methods for training of mental health clinicians providing treatment services to veterans with PTSD. The randomized controlled trial (RCT) design is briefly as follows: eligible clinicians in the community and VHA will be randomly assigned in equal numbers to three parallel intervention condition: a) Web-based training plus web-centered supervision; b) Web-based training alone; and c) Training-as-usual control group. An equal number of clinician trainees from VHA (N=219) and the community (N=219) will be recruited and enrolled in the study over an 18-month period according to a randomized, stratified 24-week design. Comprehensive assessments will be performed at baseline (T0), completion of training (T1), and at 3 month follow-up (T2). Participants randomized to the consultation condition will be exposed to a newly developed web-centered form of learning consultation. Measures of compliance and completion will assess adherence to protocol. Training effectiveness will be evaluated by means of a combination of objective (SPE) and self-report measures.

The primary and secondary aims of the study are as follows:

Primary Aim: To compare an enhanced, internet-based training intervention combined with novel web-centered supervision, internet-based training intervention without web-centered supervision and a wait-list control with regard to improvements in two CBT-based skill areas (behavioral task assignment and case conceptualization). We hypothesize that enhanced, internet-based training in conjunction with web-centered supervision will result in superior skills acquisition compared to internet training alone and that internet training alone will result in superior CBT skills than wait-list control.

Secondary Aim #1: To compare improvements in knowledge and attitudes following internet-based training with or without web-centered supervision and the control. We hypothesize that web-centered supervision will lead to greater improvements in CBT knowledge and perceived self-efficacy compared to internet-based training without supervision or a written training-only condition. We hypothesize similarly that internet-based training will be associated with improved outcomes in CBT knowledge and attitudes compared to a written training-only condition.

Secondary Aim #2: To compare improvements in skills acquisition in knowledge and attitudes following training in clinicians recruited from VHA mental health treatment settings compared to those providing services in civilian community-based clinics. We hypothesize that comparable improvements will be achieved in the trainees from civilian community-based clinics compared to clinicians recruited from VHA centers.

Secondary Aim #3: To assess the relative efficiency of training, as measured by total time required for training in each condition, in addition to self-reported level of burden for clinicians. We hypothesize that internet-based training with or without web-centered supervision will be associated with increased time investment and burden relative to training-as-usual, but that absolute levels of burden will be low in the web training conditions.

This study will be the first of its kind to systematically compare web-based training interventions across treatment settings and provider groups (VHA vs Non-VHA).The study will also be unique in: 1) developing and testing of new web-enhanced training modules and a novel web-centered supervision model recently proposed by Fairburn & Cooper (2011); 2) development and implementation of a new patient-reported measure of clinician skill and competency; and 3) assessment of post-training maintenance of skills beyond the training period. Our focus on broad-based, generic CBT skills rather than more narrowly focused protocol-based skills is another innovative aspect of our proposed study. Finally, the use of standardized patient methodology for assessing outcomes of training, and planned comparisons with self-report and knowledge-based assessment, is another novel feature of our proposed study.

If successful, the study will promote a better standard of care for psychological health of Veterans and their families by evaluating technical feasibility of two training models in evidence-based skills for PTSD treatment providers and measuring their outcomes and effectiveness. If successful, the study will provide experimental support for broad implementation of these enhanced new training methods across a variety of treatment settings.

BODY

This section of the report will describe the research accomplishments associated with each task outlined in the approved Statement of Work (SOW). As stated in our SOW, the major tasks to be accomplished in year 3 were:

Develop Data Management System

A. Ongoing monitoring of study process

i. Between years 2 and 3 of this project, the team has actively monitored data collection, data management, and the study process. We have developed bi-weekly reports for active tracking of recruitment and study processes, and meet bi-weekly to discuss progress. Study enrollment was completed in April 2015 with a total of 420 participants (VA = 209, Community = 211).

Develop Standardized Patient Rating Protocol

A. Develop and Pre Test Standardized Patient (SP) Rating Guide

i. The team has developed the SP Rating Guide in year 2. During year 3, rating scales have been developed and finalized.

B. Standardized Patient (SP) Ratings

i. During year 3, raters have been utilizing the finalized rating forms to rate the SPs from BTA and CA. These ratings have undergone and continue to undergo analyses for inter-rater reliability.

C. Training of Independent Study Raters to Concordance

i. The team has hired and trained study raters for BTA and CA. Blinded independent ratings and reliability assessents began in Q2 of Year 2.

Develop Data Collection, Intervention and Standardized Patient Interviews

A. Web Screening of Potential Clinician Applicants

B. Schedule and Carry Out SP Baseline Interviews with Eligible Clinicians

C. Automated Random Assignment of Participant with Completed SP Interview by Web Program to Web-Course, Web-Course + Web- Based Supervision, or Control

D. Participants Complete Assigned Condition

i. Web course participants

ii. Web course + web-based supervision

iii. Control Condition

E. Schedule and Carry Out Post Training, Follow Up SP Interviews

i. This is an ongoing occurrence into year 3. Completion is scheduled for Q4 2015.

Current recruitment information is as follows (as of 10/13/2015):

Registration Statistics

1609 registrant

Screener Statistics

Out of 1609 *registrants…*

998 participants have screened eligible

68 participants have screened ineligible

543 participants have not screened

Consent Statistics

Out of 998 *participants screened eligible…*

856 participants have consented

64 participants have not consented

78 participants have not completed the consent

Pre-test Statistics

Out of 856 *participants consented…*

613 participants have completed the pre-test

Standardized Patient 1 Statistics

Out of 613 *participants who completed the pre-test…*

420 participants have completed the SP1

Randomization Statistics

Out of 420 *participants who completed the SP1…*

420 participants have been randomized

66 participants have been randomized but have decided to not partake in the study (early termination)

Post-test/SP2 Statistics

Out of 420 *participants who were randomized…*

273 participants have completed the SP2

241 participants have completed the post-test

Follow-up Statistics

Out of the 420 participants who have been randomized …

224 participants have completed the Follow-up

Standardized Patient 3 Statistics

Out of 420 participants who have been randomized…

244 participants have completed the SP3

Analysis and Evaluation

A. Monitor Data Collection Rates and Data Quality

i. The team continues to collaborate with the VHA NCPTSD to monitor the collection rates and data quality on a weekly basis.

B. Create Interim and Final Analytical Data Sets

i. During the second year of this project, the initiation of the data sets was scheduled to begin. This task will continue to occur into year 4. The team has initiated discussion on what the data sets should consist of, and has begun weekly scheduled discussions on data cleaning and analysis plans. A statistical analysis plan is in the process of being developed.

KEY RESEARCH ACCOMPLISHMENTS

- Web-based and written training materials were finalized
- Video elements were implemented into the training website
- Training website was launched, to include Behavioral Task Assignment & Chain Analysis and Case Formulation
- CE accreditation has been obtained for Psychology, Social Work, Nursing, and CME
- Standardized Patient Interview scripts were finalized, and actors were hired and trained
- Pre-test, post-test, and follow-up questionnaires were developed, finalized, and programmed
- All data collection forms were finalized, programmed, and tested in the data management system
- Reports to review ongoing statuses of all forms and subject progress were developed and finalized
- Subject recruitment methods were finalized and recruitment was started (ongoing)
- Subject management procedures for the entire study flow, including all email and phone communications were developed and are ongoing
- IRB approval has been sought and obtained for all necessary modifications, and continuing review approval was obtained
- The study was launched, and has so far randomized 194 of 414 participants (as of September 17th, 2014). All participants are anticipated to be randomized by Q2 of Year 3.
- Recruitment goals were exceeded with a final randomization number of N = 420.

During the upcoming performance period, year 4, the team will focus on the following activities and milestones:

1. Ongoing monitoring of study progress – We will monitor the last remaining participants to complete data collection at all three timepoints of the study.
2. Perform blinded independent ratings and reliability assessments – We will continue blinded independent ratings and ongoing monitoring of inter-rater reliability.
3. Post-Training Assessment Review and Follow-Up – Based on the established recruitment plan, all post-test and follow-up questionnaires will be completed in October 2015.
4. Create interim and final analytic data sets – Data sets are being finalized and details foof the statistical analysis plan (SAP). This task will continue into Year 4.
5. Perform all analyses according to specification – During Year 4, the team will finalize SAPs for each proposal and perform statistical analyses to address study aims (above).
6. Author and co-author evaluation findings – During Year 4, findings will be analyzed and discussed in developed manuscripts. We anticipate submitted 3-4 papers prior to the termination of the grant.

7. Convene advisory meeting and project review – During Year 4, the team will review study achievements and lessons learned.

To date there have been no risks or unanticipated issues associated with this project that have impeded its performance.

Personnel receiving salary from this research effort are Raymond C. Rosen, Ph.D. (Partnering PI), Lisa Marceau, MPH (Co Investigator, Director), Ashley Wilkinson (Project Manager), Gayatri Ranganathan, MS (Statistician), Bernet Kato (Statistician), Julia Coleman (Research Associate), Julia Dwyer (Research Assistant), Shreya Divatia (Data Manager).

REPORTABLE OUTCOMES

Dr. Rosen presented an update on the project to CDMRP leadership at the MOMRP meeting in Ft. Detrick on September 11, 2015. The project update was well received and no concerns were raised regarding timelines or completion of the project.

All presentations to date:

Title	Presenter	Conference Dates
A Randomized Control Trial of Online Training for PTSD	Alie, G. & Graham, B.C.	April 2013
Actor Fidelity and Training for Standarized Patient use in Clinical Research	Jordan, K.R. & Graham, B.C.	April 2014
Web-centered Consultation for Online Training in PTSD Treatment: A Scalable Approach to Skill-building	Sardarian, S. & Graham, B.C.	April 2014
Individual and Organizational Factors in Dissemination and Implementation of Skills following an Online Training for Clinicians Treating PTSD	Graham, B.C., Ruzek, J. & Lee, J. E.	May 1 – May 3, 2014
Randomized, Controlled Trial of CBT Training for PTSD Providers: Project OUTFIT	Ruzek, J. & Rosen, R.	August 5 – August 6, 2014
Project OUTFIT: Online User Training for Intervention in Trauma	Graham, B.C. & Ruzek, J.	April 28, 2015
The Role of Organizational and Provider Factors in Community Interventions Across Diverse Systems.	Graham, B.C.	June 1, 2015
Randomized, Controlled Trial of CBT Training for PTSD Providers: Project OUTFIT	R. Rosen	September 11, 2015
Improving the Efficiency of Standardized Patient Assessment of Clinician Fidelity: A	Graham, B.C.	September 25 – Septmber 26, 2015

Comparison of Automated Actor-based and Manual Clinician-based Ratings		

CONCLUSION

This training program will focus on development of evidence-based CBT skills to improve skills in providers treating Veterans and active duty military and to effectively engage patients in the treatment process. This innovative study will add new knowledge to our understanding of skills dissemination in PTSD provider care. We will test the hypotheses of the study in a rigorous, experimental design, and will assess outcomes of new web-based training modules and consultation methods. This study will provide data to assist researchers, military leaders, and treatment providers to better understand practical and theoretical implications for future training of mental health providers in the VAH and other health systems.

All major milestones were met in the past 12 months of grant activity.

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Proposal ID, Funding Source: W81XWH-12-1-0532

PI: Ray Rosen **Org:** New England Research Institutes, Inc. **Award Amount:** $1,483,750.00

Study/Product Aim(s)

The purpose of this study is to design, implement and evaluate a web based training program providing skills-oriented continuing education for mental health professionals.

- To compare improvements in knowledge and attitudes following internet-based training with or without web-centered supervision and the control.
- To compare improvements in skills acquisition in knowledge and attitudes following training in clinicians recruited from VHA mental health treatment settings compared to those providing services in civilian community-based clinics.
- To determine whether clinician implementation of skills assessed by means of a novel, patient-based measure of clinician skills implementation and effectiveness is predictive of changes in an objective (i.e., standardized patient) measure of skills
- To assess the relative efficiency of training, as measured by total time required for training in each condition, in addition to self-reported level of burden for clinicians.

Approach

The study will test a large-scale, Web-based method of training with 414 VA (*n* = 207) and community-based clinicians (*n* = 207). Subjects will be recruited to participate in the evidence-based skills training and will be randomly assigned to 1 of 3 groups: Interactive Web-based training only; interactive Web-based training plus post training Web-based consultation; or training as usual control. Effectiveness will be evaluated using an intent-to-train design. Post-training and 3-month follow up assessment will be conducted.

The objective is to learn ***whether novel, internet-based training methods, with or without web-centered supervision, may provide an effective means to train increasing numbers of mental health providers in relevant, evidence-based clinical skills***.

Accomplishments: Monitoring of data collection, data management and study processes continues.. Recruitment goals were exceeded by enrolled 209 VA participants and 211 Community participants. Standardized Patient Rating are in the process of being conducted. Data collection will be completed in Q4 2015.

Timeline and Cost

Activities	CY12/CY13	CY13/CY14	CY14/CY15	CY15/CY16
Develop Web-based Training Materials				
Develop, Pre-Test and Finalize Web Site including Audio and video				
Develop / Finalize Study Protocol Measures				
Develop Data Management System				
Prepare SP Rating Protocol				
Data collect, Intervention, SP Interviews				
Analyses and manuscripts				
Estimated Budget	484,649	301,479	271,330	426,292

Updated: (19Oct2015)

Goals/Milestones

CY12 Goal – Develop SP and Consultation protocols, design web program, develop DM System

- ❑Content completed
- ❑Video/audio created
- ❑SP scripts developed
- ❑Site programmed and tested
- ❑DM system developed

CY13 Goals – Data collection

- ❑Track metrics for subject recruitment and completion goals

CY14 Goals – Data collection

- ❑Track metrics for subject recruitment and completion goals

CY15 Goals/CY16 Goals – Analyses and manuscripts

- ❑Complete main results analyses and MS based on findings

Comments/Challenges/Issues/Concerns

Currently slightly over budget. For Y04, labor hours are being carefully monitored

Projected expenditure – 1,057,457

Actual Expenditure: $1,078,948